

**PAUL JOSEPH**  
**Special Assistant U.S. Attorney**  
**U.S. Attorney's Office**  
**901 Front Street, Suite 1100**  
**Helena, Montana 59626**  
**Phone: (406) 457-5120**  
**Phone: (240) 716-2531**  
**FAX: (406) 457-5130**  
**Email: paul.joseph@fda.hhs.gov**

**ATTORNEY FOR PLAINTIFF**  
**UNITED STATES OF AMERICA**

**IN THE UNITED STATES DISTRICT COURT**  
**FOR THE DISTRICT OF MONTANA**  
**BUTTE DIVISION**

<b>UNITED STATES OF AMERICA,</b>  <b>Plaintiff,</b>  <b>vs.</b>  <b>CANADADRUGS.COM LTD.</b> <b>PARTNERSHIP,</b> <b>ROCKLEY VENTURES LTD., and</b> <b>RIVER EAST SUPPLIES LTD.,</b>  <b>Defendants.</b>	<b>14-CR-27-BU-DLC</b>  <b>OFFER OF PROOF</b>
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Plaintiff, United States of America, by and through counsel of record, Paul Joseph, Special Assistant United States Attorney for the District of Montana, hereby files its Offer of Proof.

## **THE CHARGES**

The Defendants Canadadrugs.com Ltd. Partnership, Rockley Ventures Ltd., and River East Supplies Ltd. (hereinafter, “Defendants”) are charged in a Superseding Information filed on December 12, 2017, with, in or about January 2009 through 2012, introducing, and delivering for introduction, into interstate commerce misbranded drugs, with intent to defraud and mislead, contrary to 21 U.S.C. §§ 352(c), 352(o), and 352(f)(1), in violation of 21 U.S.C. §§ 331(a) and 333(a)(2), and aiding and abetting, in violation of 18 U.S.C. § 2 (Count I).

Defendants Rockley Ventures Ltd. and River East Supplies Ltd. are charged with, between November 2011 and January 2012, selling, and causing to be sold, counterfeit drugs, namely counterfeit Avastin, in violation of 21 U.S.C. §§ 331(i)(3) and 333(a)(1), and aiding and abetting, in violation of 18 U.S.C. § 2 (Count II).

The Superseding Information also includes a forfeiture allegation, pursuant to 18 U.S.C. § 982(a)(7)(C) and 28 U.S.C. § 2461(c).

## **PLEA AGREEMENT**

There is a plea agreement in this case; the Defendants will plead guilty and waive formal presentment of an Indictment to a Grand Jury.

The United States presented any and all formal plea offers to the Defendants in writing. The plea agreement entered into by the parties and filed with the court represents, in the government's view, the only and most favorable offer extended to the defendant. *See Missouri v. Frye*, 132 S.Ct. 1399 (2012).

Pursuant to the plea agreement, governed by Rule 11(c)(1)(C), *Federal Rules of Criminal Procedure*, all three corporate Defendants will plead guilty to Count I of the Superseding Information, and Defendants Rockley Ventures Ltd. and River East Supplies Ltd. will plead guilty to Count II of the Superseding Information.

### **PENALTIES**

For the felony charge in Count I, the offense carries a maximum punishment of five years probation, and a fine of twice the gross amount of the pecuniary gain.

For the misdemeanor charge in Count II, the offense carries a maximum punishment of five years probation, and a fine of twice the gross amount of the pecuniary gain.

### **ELEMENTS**

In order for the Defendants to be found guilty of the charge of introduction, or delivery for introduction, into interstate commerce of misbranded drugs, contrary to 21 U.S.C. §§ 352(c), 352(o), and 352(f)(1), with the intent to defraud or

mislead, as charged in Count I of the Superseding Information, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2), and aiding and abetting, in violation of 18 U.S.C. § 2, the United States must prove each of the following elements beyond a reasonable doubt:

First, the Defendants introduced into, or delivered for introduction into, interstate commerce drugs;

Second, the drugs were misbranded at the time of their introduction or delivery for introduction; and

Third, the Defendants acted with the intent to defraud or mislead.

In order for Defendants Rockley Ventures, Ltd., and River East Supplies, Ltd., to be found guilty of the misdemeanor charge of sale of, or holding for sale, counterfeit drugs, namely the drug Avastin, as charged in Count II of the Superseding Information, in violation of 21 U.S.C. §§ 331(i)(3) and 333(a)(1), and aiding and abetting, in violation of 18 U.S.C. § 2, the United States must prove each of the following elements beyond a reasonable doubt:

First, the Defendants sold, or held for sale, drugs; and

Second, the drugs were counterfeit.

## **ANTICIPATED EVIDENCE**

If this case were tried in United States District Court, the United States would prove the following:

### **A. The Food Drug and Cosmetic Act.**

The United States Food and Drug Administration (“FDA”) is the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (“FDCA”). FDA’s responsibilities under the FDCA include regulating the manufacture, labeling, and distribution of all drugs and drug components shipped or received in interstate commerce, including the wholesale distribution of prescription drugs. To meet those responsibilities, FDA enforces statutes which require that drugs bear labels and labeling that enable health care providers and consumers to use them in a safe manner and that the drugs are listed by and manufactured in facilities registered with the Secretary of the United States Department of Health and Human Services. 21 U.S.C. §§ 352(f), 352(o), 352(c), and 360(i).

The FDCA establishes that a drug is deemed to be “misbranded” if it does not meet certain requirements of the statute, including if its labeling fails to bear adequate directions for use, 21 U.S.C. § 352(f), if information required to appear

on the label is not in the English language (unless distributed in Puerto Rico or U.S. territory), 21 U.S.C. § 352(c), 21 C.F.R. § 201.15(c)(1), or if it was manufactured in a foreign drug establishment and it was imported into the United States even though it was not listed with FDA, 21 U.S.C. §§ 352(o), 360(j). In the case of a prescription drug, a drug is also misbranded if its label fails to bear the symbol “Rx only.” 21 U.S.C. §§ 353(b)(4)(A), 21 C.F.R. § 201.100(b)(1).

The FDCA prohibits the introduction, or causing the introduction, of misbranded drugs into interstate commerce. 21 U.S.C. § 331(a). The FDCA also prohibits the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug. 21 U.S.C. § 331(i)(3).

## **B. Defendants’ Criminal Conduct**

In 2001, Canada-based Kristjan Thorkelson founded CanadaDrugs.com Partnership and related corporate entities (hereinafter, “Canada Drugs”) as an online pharmacy that illegally imported unapproved and misbranded prescription pharmaceutical drugs into the United States from abroad and sold the drugs illegally to consumers throughout the United States. The drugs were illegally imported into the United States through the systematic use of fraudulent customs declaration forms, which consistently undervalued the price of the drug products in order to avoid detection by United States regulatory and law enforcement

authorities. The prescription drugs distributed in the United States by the Defendants were not approved by the FDA, and were misbranded as defined in the Food Drug and Cosmetic Act pursuant to 21 U.S.C. §§ 352(c), 352(o), and 352(f), as the products contained language on the labeling that was not in English, failed to contain adequate warnings and required statements, and lacked adequate directions for use. Employees and executives of the Defendants were aware that they were selling prescription drugs in the United States that were not approved by the FDA.

In addition to being the Canada Drugs CEO, Thorkelson was also listed as the Director of Global Drug Supply, a subsidiary of Canada Drugs. Ronald Sigurdson was the Chief Financial Officer of Canada Drugs, and he assisted in the management of distribution operations along with Canada Drugs Clinical Manager Troy Nakamura, and Director of Clinical Sales for Canada Drugs, Darren Chalus. James Trueman served as a liaison between Canada Drugs and the drop shippers used by the corporate Defendants in the United States. Thomas Haughton was the President of two entities related to Canada Drugs, and he helped manage the operations of Canada Drugs' affiliate in the United Kingdom.

After approximately eight years of operating this illegal scheme, in 2009, Canada Drugs expanded its market to include acquiring prescription drugs, including life-saving cancer medication, intended for sale in foreign countries, and

illegally smuggling the drugs into the United States for distribution. As part of this expansion, Canada Drugs acquired other companies engaged in similar illegal prescription drug importation and distribution activities, and used the brand names, drug inventories, and customer lists of those companies to further its illegal operation.

Starting in 2009, executives of the Defendants, Thorkelson, Haughton, and Chalus, negotiated for the purchase of MHCS from Montana resident Paul Bottomley. The transaction was finalized in October 2010, when Bottomley sold MHCS for \$5 million to Canada Drugs and Rockley Ventures, a new entity created by Canada Drugs to operate its new clinical line of products. As part of the sale of MHCS, all non-FDA approved pharmaceutical drugs were shipped from Montana to Canada or to a shipping company in the United States under contract with the Defendants. After the purchase of MHCS, the Defendants continued to use MHCS' bank account at First Montana Bank to deposit funds from physicians for sales of unapproved and misbranded prescription drugs purchased in the United States from the Canada Drugs network of clinical sales. The funds from that account at First Montana Bank were then transferred to accounts of the corporate Defendants in Canada and Barbados.

During the criminal investigation, it was discovered that the Defendants had distributed in the United States counterfeit cancer drug Avastin (American version) and counterfeit cancer drug Altuzan (Turkish version). Specifically, the counterfeit Altuzan was distributed in 2011 by River East Supplies, a United Kingdom-based subsidiary of Canada Drugs which primarily supplied the clinical arm of Canada Drugs with products for shipment to the United States. Authorities were only able to track a portion of the counterfeit packs of Altuzan because River East Supplies did not maintain adequate drug tracing and transaction documents. Substance analysis conducted by the FDA revealed that the Altuzan vials were counterfeit as they contained no active ingredient.

The counterfeit Avastin distributed by Canada Drugs-affiliated entities was discovered in December 2011, when the United Kingdom Medicines and Healthcare Products Regulatory Agency notified the FDA of a potential counterfeit batch of oncology drug Avastin that River East Supplies had purchased from a supplier in the European Union. Specifically, River East Supplies had acquired 167 packages of Avastin 400 mg and had transferred 41 of those packs to a drop shipper used by the Defendants in the United States. That drop shipper confirmed that they had already sold and shipped 36 of the 41 vials of Avastin to physicians in the United States. Subsequent lab tests confirmed that the Avastin was

counterfeit and contained none of the active ingredient bevacizumab that is found in legitimate versions of the oncology drug.

By at least early 2012, the Defendants were aware that the Canada Drugs affiliated companies had sold packages of suspect Avastin and Altuzan to medical clinics in the United States. Yet, at that time, the Defendants failed to notify any authorities regarding the suspect product. Further, the Defendants took steps to conceal the same. For example, in December 2011, one employee of the Defendants contacted a medical practice that had purchased a supply of the suspect Avastin and requested that the office return the product. The employee falsely stated that there was no problem with the product, and the medical practice was never told that the cancer medication was suspected of being counterfeit. Additionally, in March 2012, Canada Drugs CEO Thorkelson sent an email message to all Canada Drugs employees falsely stating that Canada Drugs had “absolutely no connection to selling or offering Avastin.” Thorkelson further falsely stated in that email message that Canada Drugs sold “only prescription maintenance medications to individuals.” By the time that email message had been sent, executives of the Defendants were aware that the statements in that message were false, and that the Defendants had already taken efforts to recall the suspect Avastin from customers in the United States.

In July 2013, FDA Office of Criminal Investigation agents learned that executives and employees of the Defendants systematically undervalued the declared value of each shipment of pharmaceutical drugs on customs forms in order to conceal the illegal importation of the unapproved and misbranded drugs into the United States. Even after the drop-shippers used by the Defendants questioned the valuation of the products on the customs forms as well as the listing of the contents of the packages, an executive of the Defendants falsely informed the drop shipper that the Defendants were following all legal requirements for the importation of the drugs into the United States.

DATED this 9th day of April, 2018.

KURT G. ALME  
United States Attorney

/s/ Paul Joseph  
Special Assistant United States Attorney  
Attorney for Plaintiff

## **CERTIFICATE OF COMPLIANCE**

Pursuant to D. Mont. LR 7.1(d)(2) and CR 12.1(e), the attached United States Offer of Proof proportionately spaced, has a typeface of 14 points or more, and has a body containing 2,124 words.

/s/ Paul Joseph

Special Assistant United States Attorney  
Attorney for Plaintiff